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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,305	06/27/2003	Liang C. Dong	ARC 3251 R1	8986

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EXAMINER	
LANDAU, SHARMILA GOLLAMUDI	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,305	DONG ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 13-36* is/are pending in the application.

4a) Of the above claim(s) *2,3,14-16 and 25-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-13 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 5/4/07 is acknowledged. Claims 1-10 and 13-36 are pending in this application. Claims 1, 4-13, and 17-23 are directed to the elected invention. Claims 2-3, 14-16, and 25-36 are withdrawn as being directed to a non-elected invention and species. Claims 11-12 stand cancelled.

Claim Rejections - 35 USC § 102

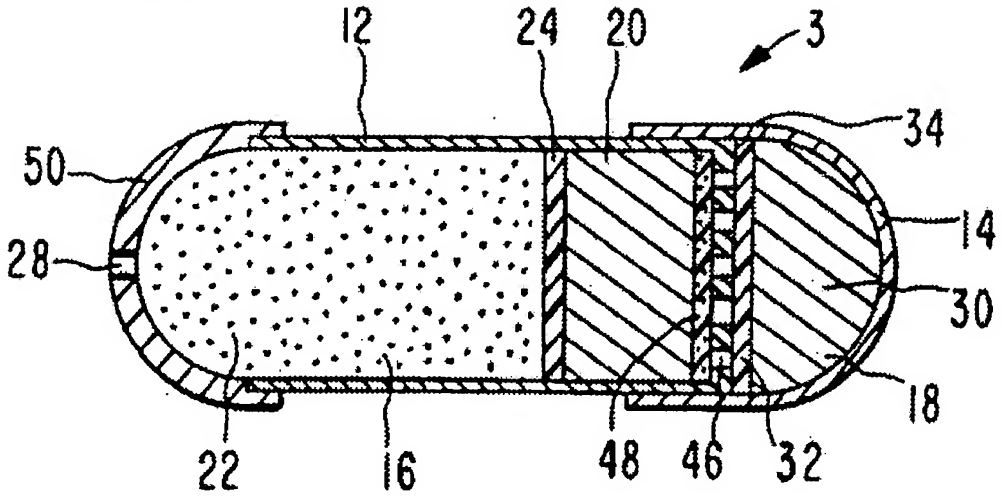
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 4, 10 under 35 U.S.C. 102(b) as being anticipated by 5,897,874 (Steven et al) is withdrawn in light of the amendments of 5/4/07.

Claims 1, 4, 10, 13, 17, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong (5,312,390).

FIG.5



Wong discloses a osmotic device comprising a reservoir formed of wall (12) and (50) and housing a drug (16). Wong discloses wall (12) is made of an impermeable or an semipermeable membrane. See column 5, lines 55-60 and column 5, lines 55-60. Cap (5) is made of an impermeable or semipermeable material. See column 5, lines 45-46. Wong further discloses the delivery device is formulated by coating two portions of a hard gelatin capsule with an impermeable material and the other portion with semi-permeable material (this other portion is implicitly wall 14 since Wong discloses at least a portion of 14 has to be semipermeable). See column 10, lines 40-60. Note the gelatin layer reads on the "water permeable layer" of claim 4, i.e. forming the multilayer reservoir. The active is delivered as a liquid, solid, or semi-solid. See column 6, lines 59-60. The reservoir further houses a osmotic expandable, push layer (20) and (30) wherein a semi-permeable membrane (46) covers a portion of the expandable, push layer (20). At least a portion of wall (14) must be semi-permeable. See column 5, lines 53-55. (28) is the exit orifice.

With regard to claim 11-13, the expandable, push layer is not completely encapsulated by wall (12) and (50) since portions of the surface are open by the screen (46). Thus, the semi-permeable membrane (46) forms over portion of the expandable, push layer that is not enclosed by the reservoir wall (12). Alternatively, both (20) and (30) which are expandable composition and are interpreted to make-up the instant expandable push layer and a portion, i.e. (30) is not enclosed by the reservoir (12) and (50) and a portion (20) is positioned in the opening of the reservoir.

Response to Arguments

Applicant's arguments filed 5/4/07 have been fully considered but they are not persuasive.

Applicant argues that Wong does not disclose, "an expandable osmotic composition positioned within an opening of the reservoir, with the reservoir and the opening configured such that the expandable osmotic composition is not completely encapsulated by the reservoir," as recited in claim 1. Applicant argues that a first object is completely encapsulated by a second object if the first object is completely positioned within the second object. There is nothing about the phrase "completely encapsulated" that suggests that the second object, which encapsulates the first object could not have pores. Applicant argues that Wong teaches that screen (46) is molded or otherwise formed as a continuous portion of the first housing (12) (col. 5, lines 26-27). Applicant argues that therefore, the osmotic composition is completely encapsulated by the reservoir.

The examiner respectfully disagrees. Independent claims are directed to the osmotic portion that is "not completely encapsulated by the reservoir". As set forth in the rejection, the

expansion layer, 20, is made of osmopolymers that interact with water and aqueous biological fluids and swell or expand to an equilibrium state and thus reads on instant "osmotic composition". See column 6, lines 1-16. Further, the screen, 46, is a continuous portion of the wall 12, which reads on instant reservoir. This reservoir has areas that are open as denoted by Figure 5 and column 5, line 28-30. Thus, the openings expose a portion of the osmotic layer and accordingly the osmotic composition is not ***completely*** encapsulated by the reservoir.

Moreover, as set forth in the office action, an alternative interpretation is that both expansion layers 20 and 30 make-up the "osmotic composition" since the claims do not exclude other components within the osmotic portion such as the screen (46) and push plate (32). Therefore, in this interpretation wherein 20 and 30 read on the osmotic composition, a portion of the composition, i.e. 30, is not encapsulated within the reservoir, i.e. wall 12. Note this is seen in Figures 4 and 5 wherein 20 and 30 is interpreted to read on the "osmotic composition" and a portion of the osmotic composition, i.e. 30, is not encapsulated by the reservoir and a portion of the osmotic composition, i.e. 20 is positioned within the reservoir (12). Applicant has not addressed this interpretation.

Therefore, for the reasons discussed above, Wong is considered to anticipate the instant invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 and 21-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (5,312,390) in further view of Dong (WO 0035419).

The teachings of Wong have been set forth above. Wong teaches impermeable materials for which the first housing 12 may be prepared from include, for example, polyethylene, polystyrene, ethylene-vinyl acetate copolymers, Hytrel.RTM. polyester elastomers (Du Pont) and other impermeable materials known to the art. see column 10, lines 50-55.

Wong does not teach the instant impermeable polymethacrylate latex material.

Dong teaches a controlled release system comprising liquid drugs. See abstract. Dong while teaching a barrier layer that is impermeable to fluids, teaches suitable materials include latex materials such as latex of acrylate esters EUDRAGIT, polyester elastomers (Du Pont); Hytrel, etc. See page 19, lines 22-25 and page 20, lines 14-26.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize the instantly claimed impermeable material for wall (12). One would have been motivated to do so with a reasonable expectation of similar results since Wong teaches the use of any impermeable material known in the art and Dong teaches latex of acrylate esters are known materials that are impermeable to

fluids. Furthermore, Dong teaches the same impermeable materials taught by Wong and thus establishes the functional equivalency between the instant latex material and the prior art's.

Response to Arguments

Applicant's arguments filed 5/4/07 have been fully considered but they are not persuasive.

Applicant argues the merits of Wong, which have been addressed above. Therefore, since applicant has not made any other arguments, the rejection is maintained for the aforementioned reasons:

Claims 5-7, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (5,312,390) in further view of Digenis (5,672,359).

The teachings of Wong have been set forth above. As discussed above, Wong teaches when forming the device, two portions of a hard gelatin capsule may be coated, one with an impermeable material and the other with a semipermeable material.

Wong does not teach the instant hydrophilic polymer.

Digenis while teaches a hard capsule for controlled release, teaches the hard capsule made by made from hydrophilic materials such as gelatin or hydroxypropylmethyl cellulose. See column 1, lines 10-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize HPMC as the material form the capsule portion. One would have been motivated to do so with a reasonable expectation of similar results since Digenis teaches hard capsules may be made from hydrophilic materials such as instant HPMC or gelatin. Thus, a skilled artisan would have been motivated to substitute the

prior art's gelatin material with the instant hydrophilic material with a reasonable expectation of success since Digenis establishes the functional equivalency of the prior art's hydrophilic material and the instant hydrophilic material, i.e. both are hydrophilic materials that are used to form hard capsules.

Response to Arguments

Applicant's arguments filed 5/4/07 have been fully considered but they are not persuasive.

Applicant argues the merits of Wong, which have been addressed above. Therefore, since applicant has not made any other arguments, the rejection is maintained for the aforementioned reasons.

Conclusion

Claims 1, 4-13, and 17-23 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616

7/11/07